

Not Relevant

From: Steven Callen <steven.callen@bayer.com>
Sent: Tuesday, February 15, 2022 2:32 PM
To: Schmid, Emily <Schmid.Emily@epa.gov>
Cc: George Sabbagh <george.sabbagh@bayer.com>; Roe, Lindsay <Roe.Lindsay@epa.gov>; Meadows, Sarah <Meadows.Sarah@epa.gov>; BCSReg_Archive <esepamailbox@bayer.com>
Subject: RE: XtendiMax Supplemental Labels

Thanks, Emily! Nice to hear from you.

This all looks straightforward to me. We should be able to make these changes, update the master label and create an additional supplemental label, and get them to you by the end of the week at the latest. I'll submit the master label and additional supplemental through CDX as indicated, but shall I send the updated state supplemental labels directly back to you?

There was a question about the expiration date. The states reviewed these labels prior to us submitting to EPA, and they had no issues with aligning the expiration date on these with that of the XtendiMax label itself. I can confirm again with the states, but we would propose keeping the expiration date as is.

Thanks,
Steven

From: Schmid, Emily <Schmid.Emily@epa.gov>
Sent: Tuesday, February 15, 2022 11:25 AM
To: Steven Callen <steven.callen@bayer.com>
Cc: George Sabbagh <george.sabbagh@bayer.com>; Roe, Lindsay <Roe.Lindsay@epa.gov>; Meadows, Sarah <Meadows.Sarah@epa.gov>
Subject: XtendiMax Supplemental Labels

Hi Steven,

I hope you are doing well!

We have reviewed the labels for Minnesota and Iowa and have some comments (PDFs attached).

It has been decided that the best way to get this information out to the user is to have each registrant set up a website that will hold supplemental labels and add a general direction to the master label that says, "You must check [X website] for state specific restrictions within 30 days of

application of this product.” That way, if there are changes to these supplemental labels, or if other states want to add supplemental labels, the master label won’t need to be updated every time. Additionally, we’ll need a supplemental label with this direction since some of the product is already in the hands of the users and can’t be relabeled with this direction. You can submit both of those as a fast track label amendment.

Most of the comments have to do with these needing to be supplemental labels rather than bulletins, but if you have any questions about our comments or anything else, please feel free to reach out.

Best regards,
Emily

Emily Schmid
Product Manager 25
Herbicide Branch
Registration Division, Office of Pesticide Programs
U.S. Environmental Protection Agency

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